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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,081	03/03/2000	Leland Shapiro	114232.104	5429

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KATTEN MUCHIN ROSENMAN LLP
525 WEST MONROE STREET
CHICAGO, IL 60661-3693

EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,081	SHAPIRO, LELAND	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-17 and 23-30* is/are pending in the application.

4a) Of the above claim(s) *5,6,8,9 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,10,14,15 and 30* is/are rejected.

7)☒ Claim(s) *2,12,13,16 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 December 2006 has been entered.

Priority

As previously noted, the instant application is granted the benefit of priority of the 5 March 5, 1999 filing date of U.S. Provisional Application No. 60/123,167.

Status of the Claims

Claims 1-10, 12-17, and 23-30 remain in the application. Pursuant to Applicant's elections (i) of the invention of Group I, claims 1-25 drawn to a method of inhibiting apoptosis, in the Response filed 6 August 2001, and (ii) of the species of inhibitor which is the α_1-antitrypsin inhibitor in the Response filed 23 November 2001, claims 5, 6, 8, 9 and 23-25 are withdrawn from consideration as drawn to a non-elected invention where they describe protease inhibitors species other than the elected species. Claims 26-28 in Group II were canceled as well as claims 11 and 18-22. Of the examined claims 1-4, 7, 10, 12-17, and 30, (i) claims 1, 3, 4, 10, 15 and 30 had been rejected and (ii) claims 2, 7, 12-14, 16 and 17 had been objected to in view of their dependence from rejected claims in the communication mailed 29 June 2005.

Response to Amendments

While the listing of claims that accompany the Response filed 13 December 2005 indicates claim 14 as "Currently Amended", claim 14 is not currently amended and the

descriptor reflects only the amendment of 5 April 2005. The amendments to claims 1 and 3 in the Response of 13 December 2005 overcome the rejections of record stated under 35 U.S.C. §§ 102 and 112, second paragraph, in the communication mailed 29 June 2005. A further search has been conducted on the several disease states recited in claim 1 where a method of treatment that comprises an administration of either of the serine protease inhibitors of claim 3 to treat the disease would inherently, according to the disclosure of the specification, result as well in a method of inhibiting apoptosis where there is nothing in claims 1, 3, 4, 10, 15 or 30 that distinguishes an inhibition of apoptosis from a prior art method wherein an the α_1-antitrypsin inhibitor, whether a native inhibitor or the recited Met^{358} variant of α_1-antitrypsin inhibitor is administered to treat a recited disease. Because new grounds of rejection are stated herein, this communication is not made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 7, 10, 14, 15, and 30 are rejected under 35 U.S.C. § 103 as being anticipated by Ledzey et al., US 6,566,331, in view of Herbert et al., .

Ledzey et al., US 6,566,331, is available under 35 U.S.C. § 102(e) for the teaching in its priority application serial No. 09/241,754, filed 1 February 1999, that the α_1-antitrypsin inhibitor may be used to treat diseases caused by "autoimmune disorders" and that are "related to the collagen diseases". See, e.g., page 1 of the intervening PCT publication WO 00/44390 which corresponds to page one of the specification of the earlier US priority document. Ledzey et al., '331, also teach that a pharmaceutical preparation comprising the α_1-antitrypsin inhibitor and oxygen metabolite scavengers

may be introduced into a cavity containing a biological fluid at a dosage of from 10mg to 20mg per day, see pages 7-11 of the PCT publication that correspond to the disclosure of the earlier US priority document, corresponding to concentrations in the body and in a biological fluid meeting limitations of claims 4 and 14. The priority document for Ledzey et al., '331, does not teach, however, that a pharmaceutical preparation comprising the α_1-antitrypsin inhibitor and oxygen metabolite scavengers should be administered to a person in order to treat an autoimmune disorder or a collagen disease-related condition.

Herbert et al. teach that insufficient levels of human α_1-antitrypsin inhibitor to control the proteolytic activity of elastase contribute to progress of various disease conditions, including rheumatoid arthritis, particularly in persons suffering a heritable, genetic, defect in production of human α_1-antitrypsin inhibitor. See abstract and the discussions at page 809, right column, and pages 814-815. Herbert et al. teach the administration of a synthetic elastase inhibitor, however, for treating such conditions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to extend the teaching of the priority document of Ledzey et al., '331, to the treatment of the elastase-exacerbated autoimmune disease of rheumatoid arthritis, the treatment of which with an elastase inhibitor is suggested by Herbert et al., by administering human α_1-antitrypsin inhibitor to a body cavity, such as a synovial space, because Ledzey et al., '331demonstrate the efficacy of treating an elastase-exacerbated medical condition in a body cavity and because such an artisan at that time would have recognized that use of human α_1-antitrypsin inhibitor in such treatment would be safe and effective where it ordinarily is present in the human body. Since the specification teaches that the administration of human α_1-antitrypsin inhibitor in treating an autoimmune disease will inherently constitute a method of inhibiting apoptosis, the treatment obvious over the

teachings of Ledzey et al., '331 and Herbert et al. would satisfy the limitations of claims 1, 4, 7, 10, 14, 15, and 30 herein.

Claim 3 is rejected under as being anticipated by Ledzey et al., US 6,566,331, and Herbert et al. as applied to claims 1, 4, 7, 10, 14, 15, and 30 above, and further in view of Ledzey et al., US 5,134,119.

The teachings of Ledzey et al., '331, and Herbert et al., discussed above, are taken as before. Ledzey et al., '119, teach that the use of a modified human α_1-antitrypsin inhibitor comprising a substitution of an aliphatic amino acid, such as leucine, for the methionine present at position 358 in the amino acid sequence of human α_1-antitrypsin inhibitor produces an inhibitor that is resistant to oxidation and better capable of inhibiting tryptase, as well as elastase, when applied in a pharmaceutical composition to treat a person. See cols. 1-4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a modified human α_1-antitrypsin inhibitor comprising a substitution of an aliphatic amino acid, such as leucine, for the methionine present at position 358 in the amino acid sequence of human α_1-antitrypsin inhibitor taught by Ledzey et al., '119, for the native human α_1-antitrypsin inhibitor in treating an autoimmune disease. This is because it was well-known in the art at the time the invention was made that the cellular sources of the elastase and tryptase involved in the inflammatory processed of autoimmune diseases, such as rheumatoid arthritis, are mast cells of the immune system which also produce oxidants.

Conclusion

The elected and examined claims 2, 7, 12, 13, 16, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
31 March 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER